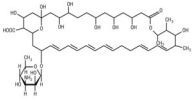


**NYSTATIN - nystatin tablet, film coated**  
TEVA PHARMACEUTICALS USA

**DESCRIPTION**

Nystatin is an antimycotic polyene antibiotic obtained from *Streptomyces noursei*. Its structural formula:



C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub> M.W. 926.13

Nystatin Tablets contain the inactive ingredients Corn Starch, Povidone, Compressible Sugar, Microcrystalline Cellulose, Sodium Starch Glycolate, Talc, Magnesium Stearate, Purified Water, and Coloring.

**CLINICAL PHARMACOLOGY**

**Pharmacokinetics**

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. In patients with renal insufficiency receiving oral therapy with conventional dosage forms, significant plasma concentrations of nystatin may occasionally occur.

**Microbiology**

Nystatin is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. *Candida albicans* demonstrates no significant resistance to nystatin *in vitro* on repeated subculture in increasing levels of nystatin; other *Candida* species become quite resistant. Generally, resistance does not develop *in vivo*. Nystatin acts by binding to sterols in the cell membrane of susceptible *Candida* species with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

**INDICATIONS AND USAGE**

Nystatin Tablets are intended for the treatment of non-esophageal mucus membrane gastrointestinal candidiasis.

**CONTRAINDICATIONS**

Nystatin Tablets are contraindicated in patients with a history of hypersensitivity to any of their components.

**PRECAUTIONS**

**General**

This medication is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitization or irritation is reported during use.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate carcinogenic potential. There also have been no studies to determine mutagenicity or whether this medication affects fertility in males or females.

**Pregnancy**

Teratogenic Effects

Category C

Animal reproduction studies have not been conducted with nystatin. It is also not known whether nystatin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin should be given to a pregnant woman only if clearly needed.

**Nursing Mothers**

It is not known whether nystatin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nystatin is administered to a nursing woman.

**ADVERSE REACTIONS**

Nystatin is well tolerated even with prolonged therapy. Oral irritation and sensitization have been reported. (See **PRECAUTIONS: General**.)

**Gastrointestinal**

Diarrhea (including one case of bloody diarrhea), nausea, vomiting, gastrointestinal upset/disturbances.

**Dermatologic**

Rash, including urticaria has been reported rarely. Stevens–Johnson syndrome has been reported very rarely.

**Other**

Tachycardia, bronchospasm, facial swelling, and nonspecific myalgia have also been rarely reported.

**OVERDOSAGE**

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset. There have been no reports of serious toxic effects of superinfections (see **CLINICAL PHARMACOLOGY, Pharmacokinetics**).

**DOSAGE AND ADMINISTRATION**

The usual therapeutic dosage is one to two tablets (500,000 to 1,000,000 units nystatin) three times daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent relapse.

**HOW SUPPLIED**

Nystatin Tablets USP, 500,000 Units are brown, film–coated tablets debossed "93"–"983" and are packaged in bottles of 100. Store at controlled room temperature , between 20° and 25°C (68° and 77°F) (see USP).

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Manufactured By:

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Manufactured For:

**TEVA PHARMACEUTICALS USA**

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